

# **MTC**

Media Trade Corporation

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## **510(k) Summary**

NOV 29 2007

Submitter's Name:	Guenter Ginsberg Media Trade Corporation
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Contact:	Guenter Ginsberg
Date of Summary:	August 10, 2007
Trade Name:	Mobil-O-Graph NG, 24 h ABP-Control
Establishment:	I.E.M. GmbH Registration No. 9617476 Cockerillstrasse 69 52222 Stolberg, Germany
Classification	System, Measurement, Blood Pressure, Non-Invasive Product Code: DXN Regulation No. 870.1130 Class: II Panel: 74 (Cardiovascular)

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Predicate Device:	<b>ABPM Mobil-O-Graph Blood Pressure Monitor</b> K 964235 Also manufactured by I.E.M. GmbH of Stolberg, Germany
Device Description:	The <b>Mobil-O-Graph NG ABPM</b> (24 hour Automatic Blood Pressure Monitor) is a fully automatic table model device that measures blood pressure by means of an inflatable cuff on the upper arm. It employs the <b>Oscillometric Principle</b> .
Intended Use:	The <b>Mobil-O-Graph NG ABPM</b> system is an automated, microprocessor controlled blood pressure monitor which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 to 48 hours.
Technological Characteristics:	<p>The <b>Mobil-O-Graph NG ABPM</b> has the same general design and performance characteristics as the predicate device from I.E.M. GmbH. The main difference is the physical size, shape and weight, as well as the option to be interfaced with regular computers via infrared or Bluetooth technology.</p> <p>The <b>Mobil-O-Graph NG ABPM</b> has the same intended use, general design and incorporates similar materials and components, hence should therefore raise no new questions of safety and effectiveness.</p> <p>This submitter concludes that the <b>Mobil-O-Graph NG ABPM</b> is therefore substantially equivalent to the predicate device "ABPM Mobil-O-Graph Blood Pressure Monitor by the same Establishment: I.E.M. GmbH of Stolberg, Germany.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 29 2007

Media Trade Corporation  
c/o Mr. Guenter Ginsberg  
President  
11820 Red Hibiscus Drive  
Bonita Springs, FL 34135

Re: K072446  
Mobil-O-Graph NG 24h ABP-Control  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive blood pressure measurement system.  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: November 14, 2007  
Received: November 15, 2007

Dear Mr. Ginsberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

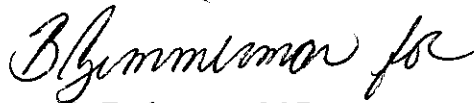
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Guenter Ginsberg

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman for".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K072446

Device Name: Mobil-O-Graph NG 24h ABP-Control

Indications For Use: The Mobil-O-Graph ABPM system is an automated, microprocessor controlled blood pressure monitor which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 to 48 hours.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bhimmanna  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K072446